

### REMARKS

Claims 25, 27 and 45-70 were pending in this application. Claims 27, 53 and 60 are amended herein. Claims 27 and 53 are amended to correct minor errors in the claims. Claim 60 is amended to delete PTX from the claim for reasons discussed below. New claim 71 is added herein. Support for the new claim is found in the specification as originally filed at, *e.g.*, page 28, lines 11-12. It is believed that no new matter has been added. Claims 25, 27 and 45-71 are currently pending, and no claim has been allowed.

#### **Formal Matters**

Applicants gratefully acknowledge the granting of the Petition to Make Special, the entry of the Request for Continued Examination, and the entry of the Supplemental Amendment dated November 3, 2003.

According to the Action, the oath or declaration is defective. A new oath is submitted herein as Exhibit C.

Applicants appreciate the full consideration of the submitted references in the Information Disclosure Statement and the return of the signed Form 1449.

The Examiner states that the application fails to comply with the requirements of 37 C.F.R. §§ 1.821 - 1.825 for one or more reasons set forth in the attached "Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequences and/or Amino Acid Sequence Disclosure." Applicants note that no such Notice to Comply was included with the response. Nonetheless, the Specification is amended herein to include sequence identification numbers. Applicants have also included a Statement Pursuant to 37 C.F.R. § 1.823(b), a paper copy and a labeled, computer readable copy of the Sequence Listing included in the instant application.

Applicants note that a review of the file history indicates that claim 27 is still pending as it has not been canceled or withdrawn by Applicants. It appears that claim 27 was inadvertently omitted in the list of pending claims in the first Office Action dated April 29, 2002, and that omission went undetected by the Office and Applicants until now. Thus, Applicants respectfully request that claim 27 be properly recognized as a pending claim.

**Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 25 and 45-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 7-13 of copending application No. 09/361,775 and U.S. Patent No. 6,410,512. According to the Examiner, the conflicting claims are not identical, but are not patentably distinct from each other because both application claim PSI for the same function but the present application broadly includes additional compounds. Claims 25 and 45-70 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 of co-pending Application Serial No. 10/050,425.

Applicants respectfully request that this rejection be held in abeyance until such time that allowable claims are identified. At that time, Applicants will file a terminal disclaimer if necessary.

Claims 25 and 45-70 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-44 of the co-pending Application No. 10/052,832. Applicants note that the '832 application is in fact the instant application. Thus, Applicants respectfully request the withdrawal of this rejection.

**Rejection Under 35 U.S.C. §102 (b)**

Claims 25 and 64-68 are rejected under 35 U.S.C. §102 (b) as allegedly unpatentable over Miyamoto (JP 62-192311). According to the Examiner, Miyamoto teaches that pentoxifylline (PTX) has a hair growth effect. Applicants respectfully traverse this rejection.

Applicants respectfully submit that pentoxifylline is not a proteasomal inhibitor. While PTX is disclosed as a proteasomal inhibitor in the specification as filed, Applicants believe that this assertion is incorrect. To the Applicants' knowledge, there has been only one report identifying PTX as a proteasomal inhibitor. The report identifying PTX as a proteasomal inhibitor is Combaret et al., *Mol. Biol. Rep.* 26:95-101 (1999). This reference is cited in the original disclosure as filed at page 29, lines 17-20 as it was published prior to the submission of the application. Applicants do not believe that Combaret's report is accurate for at least the following reasons. First, Applicants tested PTX in assays measuring proteasomal inhibition. PTX fails to inhibit proteasomal activity.

Second, no publication other than Combaret's has confirmed that PTX inhibits proteasomal activity. The art-recognized activities of PTX are as an NF- $\kappa$ B inhibitor and a phosphodiesterase inhibitor. Dr. Greg Mundy, one of the Applicants for the instant application, has attested to the absence of inhibitory activity of PTX in proteasomal assays and to the state of the art with regards to PTX activities in a Declaration Submitted Pursuant to 37 C.F.R. § 1.132 submitted herewith. *See* Exhibit D.

Hence, Miyamoto fails to teach each and every element of the claimed invention and therefore does not anticipate the claimed methods. PTX is not a proteasomal inhibitor for the reasons discussed above. Miyamoto provides no additional disclosure regarding proteasomal inhibitors or other compounds that may be useful for stimulating hair growth. In the absence of any teaching regarding proteasomal inhibitors, Miyamoto fails to anticipate the instant methods.

In view of the above, Applicants submit that the rejection under 35 U.S.C. § 102 (b) is overcome. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

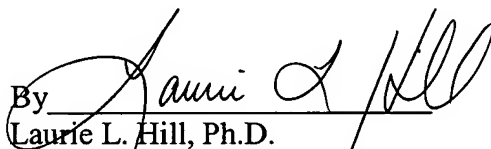
### CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 432722002612.

Dated: March 11, 2004

Respectfully submitted,

By   
Laurie L. Hill, Ph.D.

Registration No.: 51,804  
MORRISON & FOERSTER LLP  
3811 Valley Centre Drive, Suite 500  
San Diego, California 92130  
(858) 720-7955